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Unconditional IDE approval for alfapump pivotal study (POSEIDON)

Webcast & Conference Call – 4 June 2019

Today's presenters

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Regulatory Disclaimer

- The **alfa**pump® has not yet received regulatory approval in the US and Canada. Any statement in this presentation about safety and efficacy of the **alfa**pump does not apply to the US and Canada because the device is currently undergoing clinical investigation in these territories.
- Sequana Medical's proprietary DSR therapy is under development and is developing **alfa**pump DSR (Direct Sodium Removal) to deliver a convenient and fully implanted system for DSR therapy. DSR therapy is still in development and it should be noted that any statements in this presentation regarding safety and efficacy arise from pre-clinical studies and ongoing clinical investigations which have yet to be completed. There is no link between DSR therapy and ongoing investigations with the **alfa**pump system in Europe, the US and Canada.

Agenda

- Welcome and introduction
- POSEIDON – the **alfa**pump pivotal study to support approval in US & Canada
- Conclusions and next steps
- Q&A

Unconditional IDE approval for POSEIDON (alfapump® pivotal study) in just 30 days

- **alfa**pump pivotal study for treatment of **recurrent or refractory ascites** due to liver cirrhosis
- Unconditional approval by US FDA **after 30 days**
- Optimised clinical trial design in up to **50 patients implanted with alfa**pump in study cohort and **shorter time to primary endpoint** analysis
- Expected FPI in **H2 2019**
- Study intended to support **approval in US and Canada**
- Breakthrough device designation makes **alfa**pump eligible for **prioritized review** of submission package for regulatory approval in the US

We have moved forward our planned US launch of the alfapump to H1 2022

IDE: Investigational Device Exemption; FDA: Food and Drug Administration; FPI: first patient in

POSEIDON:

alfapump® pivotal study to support approval in US & Canada

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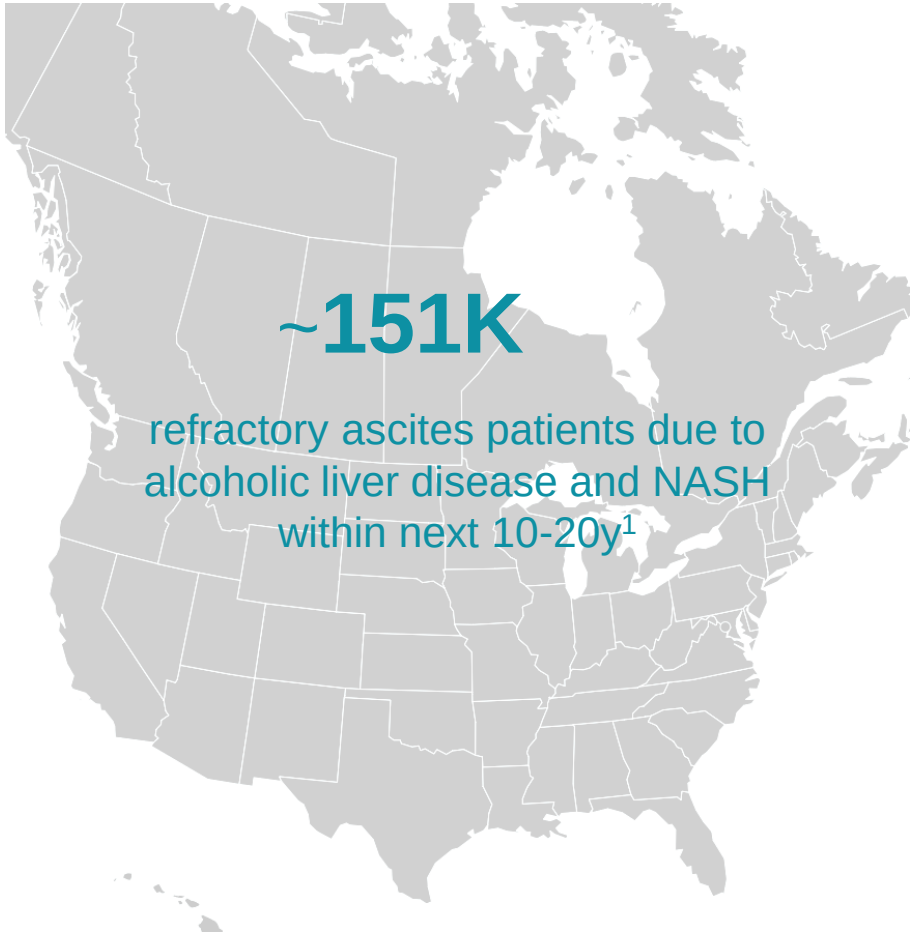
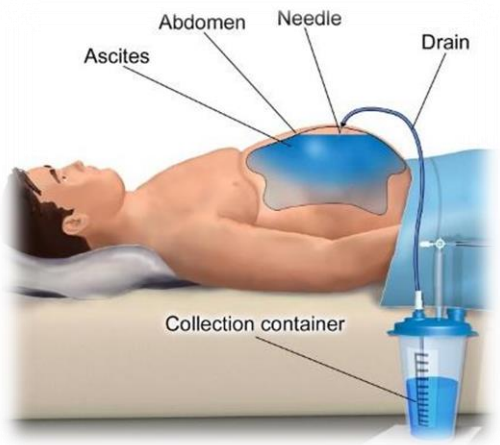
“The number of patients with recurrent & refractory liver ascites is forecast to increase dramatically due to the growing prevalence of NASH”



NASH: Non-alcoholic Steatohepatitis; Source 1: Management estimate that is inclusive of estimated growth in prevalence of NASH for the US and EU5 based on GlobalData Epidemiology Forecast to 2026.

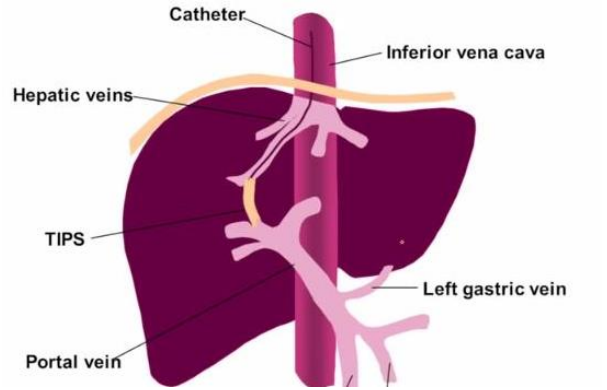
Existing therapies have severe limitations

Large Volume Paracentesis ("drainage")



Dramatically reduces quality of life

Transjugular Intrahepatic Portosystemic Shunt (TIPS)



Increased risk of encephalopathy above 65

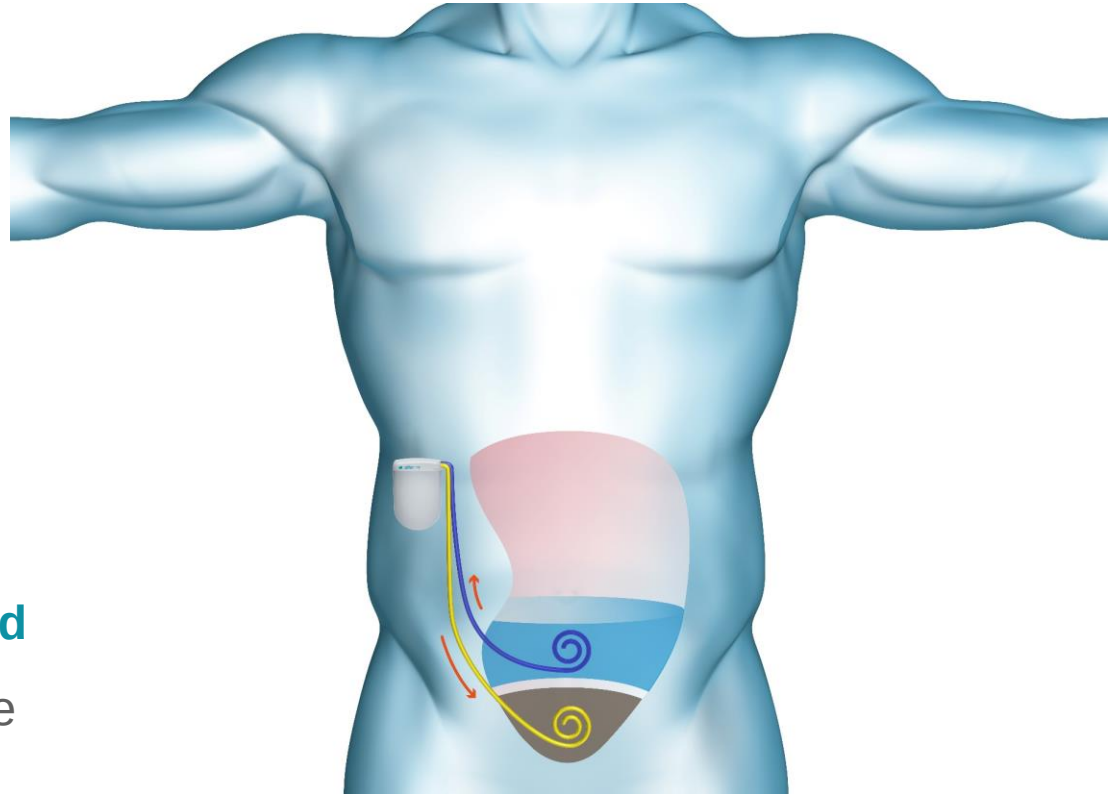
(typical age of patient with ascites due to NASH-related cirrhosis)

Liver transplant

Limited availability and high costs

Evolution of liver cirrhosis to “mainstream disease”

- NASH and NASH-related cirrhosis will become **more prevalent in mainstream society**
- We believe:
  - there are clear analogies to today’s coronary artery disease market
  - this will drive change in attitudes to liver cirrhosis, resulting in the **need for modern and convenient therapies** for chronic liver disease



POSEIDON – overview trial design

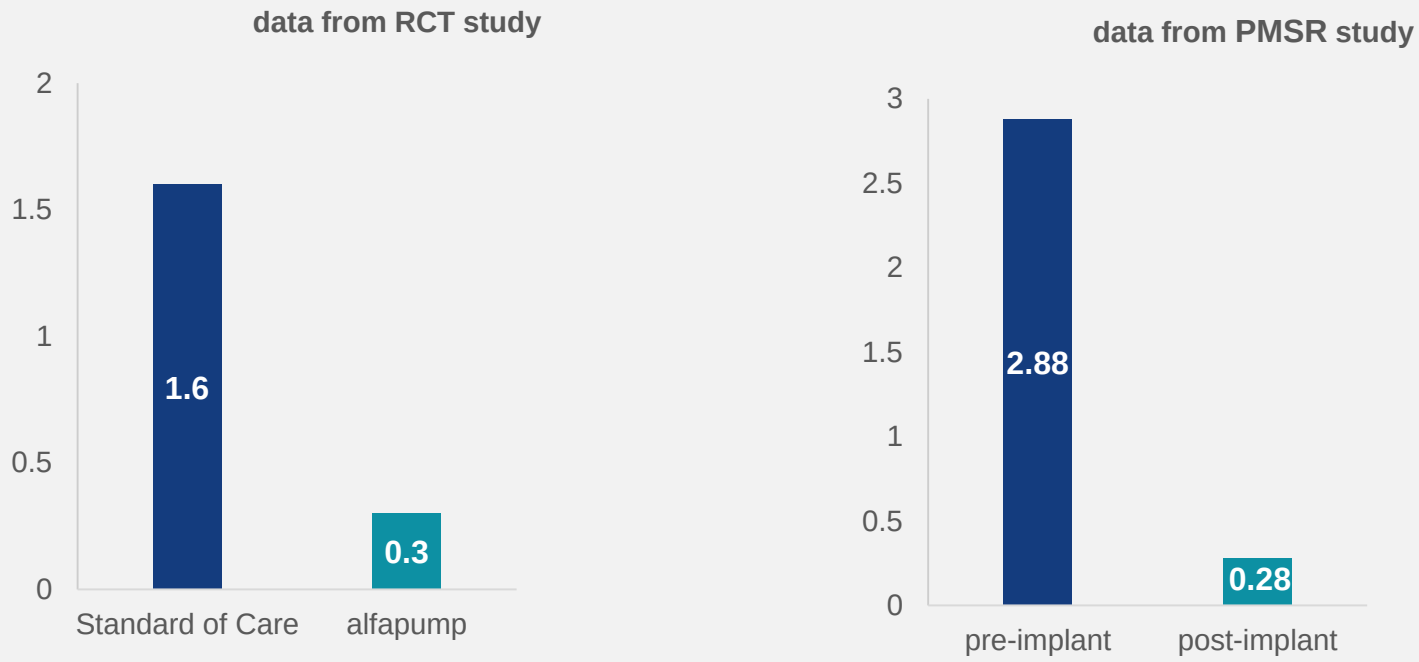
- Single arm, open-label, **within subject crossover study** ⇨ reduces risk of study drop-out / reduces sample size
- **Up to 15 centers in US and Canada** – site selection driven by clinical & reimbursement factors:
  - Clinical expertise of multidisciplinary team (hepatologist – interventional radiologist)
  - Transplant (liver) center
  - Objective data on paracenteses procedures
  - Insurance groups
- **Training in alfa**pump® **implantation** procedure for unexperienced study centers
- Enrollment of 60 patients with recurrent or refractory ascites due to liver cirrhosis in study cohort ⇨ up to **50 patients** to be implanted with **alfa**pump for primary endpoint analysis
- Primary endpoint analysis at **9 months after enrollment to the study**
- First patient in expected in **H2 2019**

POSEIDON – primary effectiveness outcome

Proportion of patients with a 50% reduction in average number of paracentesis per month in the post-implant observation period vs. pre-implant observation period

*Previous **alfa**pump studies in patients with refractory ascites due to liver cirrhosis support this efficacy endpoint:*

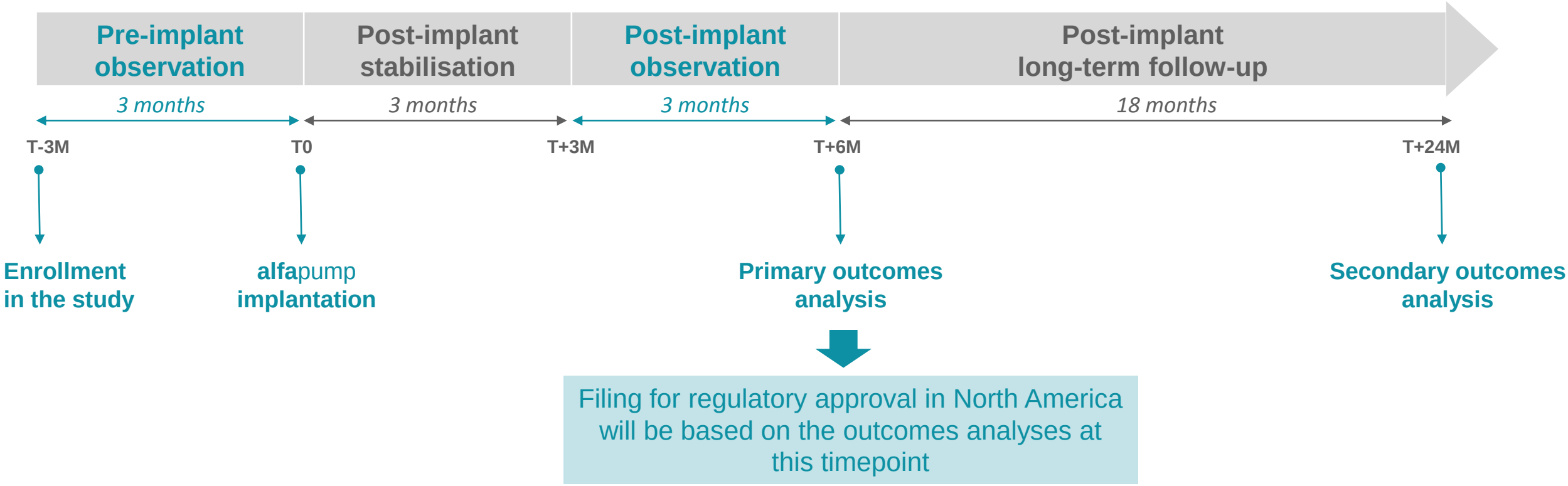
Average frequency of paracentesis per month



RCT: Randomised Controlled Trial; PMSR: Post-Marketing Surveillance Registry

POSEIDON – alfapump® pivotal study

Single-arm, open-label, within subject crossover study



POSEIDON – alfapump® pivotal study

Primary and Secondary Outcomes

Primary effectiveness outcomes:	• proportion of patients with a 50% reduction in average number of paracentesis per month in the post-implant observation period vs. pre-implant observation period • per-patient ratio of post-implant to pre-implant with respect to average monthly number of paracentesis
Primary safety outcome:	• rate of **alfa**pump related re-interventions adjudicated by the Clinical Events Committee
Secondary outcomes:	• safety (device and/or procedure-related adverse events) • quality of life (assessed by general SF-36 as well as disease-specific Ascites-Q questionnaires) • patients' nutritional status • health economics • overall survival

Proposed CMS rule on payment system for breakthrough devices is promising development for the alfapump®

CMS Plots to Increase Breakthrough Device Payments

Posted 24 April 2019 | By Zachary Brennan

The Centers for Medicare and Medicaid Services (CMS) late Tuesday proposed a new rule that would increase payments for medical devices designated by the US Food and Drug Administration (FDA) as breakthrough devices.

CMS explains how at the time of approval for these devices with a breakthrough designation, real-world data on outcomes in different patient populations is often limited. So, it can be challenging for device firms to meet the requirement for demonstrating a "substantial clinical improvement" in order to qualify for new technology add-on payments.

CMS: Centers for Medicare and Medicaid Services

Conclusions & next steps

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Three platforms for growth

Balancing risk and reward

North American Liver & Cancer

- POSEIDON pivotal study commencing in H2 2019

North America & Europe Heart Failure

- First in human studies:
  - ✓ single dose (completed)
  - repeated dose with **alfa**pump (commencing H2 2019)

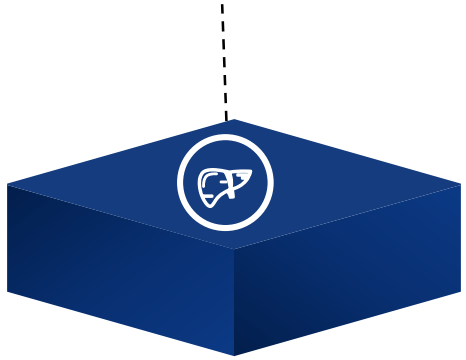
Europe Liver & Cancer

- Prospective study in malignant ascites & registry in liver
- Focused expansion in UK, DE, CH & FR

Strong newsflow since IPO

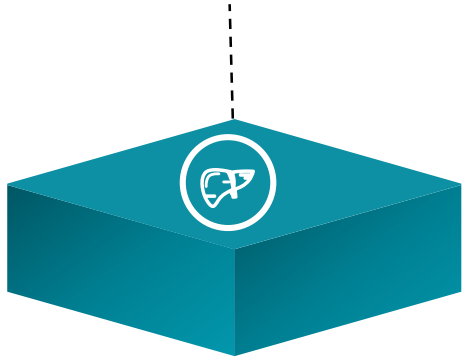
EU

alfapump® **included in German (DGVS) treatment guidelines**



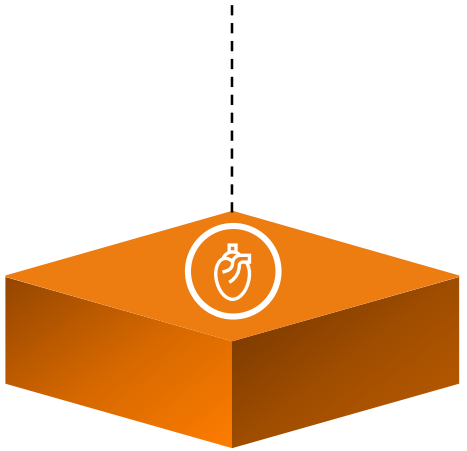
US

FDA approves IDE with optimised POSEIDON study design



HF

DSR clinical proof of concept delivered



IPO: Initial Public Offering; DGVS: German Society of Gastroenterology Digestive and Metabolic Diseases; FDA: Food and Drug Administration; IDE: Investigational Device Exemption; DSR: Direct Sodium Removal

Q&A